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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,173	06/01/2001	Beth A. Burnside		2928

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	4

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/872,173	Applicant(s) BURNSIDE ET AL.	
	Examin r Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Amendment A received on March 31, 2003 is acknowledged. Claims 1-20 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-16, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al (6,491,949).

Faour et al disclose a an osmotic device containing an drug core (7), a semi-permeable membrane surrounding core (6), a second drug layer (4), and a semi-permeable layer surrounding layer (3) (Note figure). The semi-permeable membrane is preferably made of a cellulose ester (cellulose acetate-butyrate) (col. 7, lines 23-27). The individual drug containing layers may contain from .10-99.9% of active (col. 9, lines 33-35). The active agents suitable are taught on column 13 to column 17. These actives include antihistamines, decongestants (chlorophenramine, loratidine, and asemtizole), and insulin.

Faour et al do not exemplify the recited greater concentration of the outer drug layer than the inner core.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to manipulate the conditions and general teachings of the prior art

to obtain the desired effect since Faour et al teach the active in each layer may be contained in a range of .10-99.9% and be individually varied. One would be motivated to do so depending on various parameters such as the identity and physical properties of the each drug employed, the dosage of drug employed, the desired effect of said drug, the intended application of osmotic device, and the physiological condition to be treated.

Response to Arguments

Applicant argues Faour et al's device and instant invention are fundamentally different. It is argued in the instant invention, a semipermeable layer surrounds both the core and first layer portion containing the same active agent. It is argued that the instant invention allows for zero-order release. Applicant argues that Faour et al discloses a dual osmotic agent wherein the core is surrounded by a first permeable layer, which is surrounded by another drug layer, and another semipermeable layer. It is argued that there is a lag release before release of the core.

Applicant's arguments have been fully considered but they are not persuasive. In regards to independent claim 1, the claim is unclear in the manner that it is written and can be interpreted two ways: one wall encloses both the core and layer or one wall encloses the core and another wall encloses the core. Faour et al was applied using the latter interpretation wherein a semipermeable wall encloses the core portion and another semipermeable wall encloses the layer portion. For arguendo sake even if the claim was interpreted in the first manner, the examiner points out that the claim language does not exclude additional coatings.

In regards to claim 7, the examiner points to Figure 4 wherein Faour et al teach an active core, a semipermeable membrane, a second drug, another semipermeable membrane, and an active release layer. Further, Faour teaches additional coats on the second osmotic device for controlled release. Note column 5, lines 18-35 and column 6, lines 54-60.

In regards to the argument that the instant invention contains the same active agent, the examiner points to column 5, lines 59-60 wherein Faour teaches the use of same or different drugs. Lastly in regards to the argument regarding zero order release, the examiner points out that the claims do not recite this feature. Additionally, Faour teaches zero order release on column 5, line 45.

Claims 6, 17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al (6,491,949) in view of Hamel et al (4,801,461).

The teachings of Faour et al have been set forth above. Faour et al teaches the use of decongestants and sympathomimetic drugs such as ephedrine (col. 14, lines 54-44).

Faour does not teach the use of pseudoephedrine.

Hamel teaches instant drug is a sympathomimetic amine and is used for relief of symptoms associated with the common cold (col. 1, lines 20-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate pseudoephedrine into Faour et al's device since Hamel teaches the use of instant drug to relieve cold symptoms. One would be motivated to do so with the expectation of similar results since Hamel teaches the

instant drug is a sympathomimetic amine and Faour teaches the suitability of sympathomimetic drugs in the device.

In regards to the combination therapy, it is deemed obvious to one of ordinary skill to choose drugs according to the symptoms to be treated.

Response to Arguments

Applicant arguments pertain to the primary reference, which have been addressed above.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al (6,491,949) in view of Weinstein et al (6,051,585).

The teachings of Faour et al have been set forth above. Faour et al teaches the use of decongestants and sympathomimetic drugs such as ephedrine (col. 14, lines 54-44).

Faour et al do not specify the first active being pseudoephedrine and the second active being loratidine.

Weinstein teaches a single composition containing a decongestant (pseudoephedrine) and antihistamine (loratidine) to treat rhinitis. Note example 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Faour et al and Weinstein et al and use the instant combination therapy in Faour's osmotic device. One would be motivated to do so since Weinstein teaches loratidine and pseudoephedrine provides relief for rhinitis. Furthermore, one would expect similar results since Faour teaches the use of different active agents in different layers.

Claims 1-6 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savastano et al (5,681,584) in view of Faour et al (6,004,582).

Savastano et al teach a controlled release drug delivery device. The device contains a drug core, a delay jacket, a semi-permeable membrane, an additional drug layer that is placed between the delay jacket and semi-permeable membrane (Note claim 20). The active agents that are taught to be suitable are various proteins and peptides (col. 6, lines 33-65). The semi-permeable membrane is made of cellulose acetate (example 4).

Savastano does not specify the concentration of the actives in the respective layers. The reference does not teach recited drug in claim 6.

Faour et al teach a multi-layered osmotic device wherein the device contains a drug core and external drug layer. Faour teaches the core drug may vary in amount of .1-99.9% according to the particular active used and the intended use of the device (col. 9, lines 28-36). The external coat drug contains from .1-99% varying according to the characteristics and properties of the particular drug, does, desired effect, and intended use of device (col. 6, lines 42-54). Lastly, Faour teaches pseudoephedrine (examples) and instant actives on column 14.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Savastano et al and Faour et al since both teach controlled release device and Faour teaches manipulating the amount of active contained in the device to obtain the desired effect. One would be motivated to do so depending on various parameters such as the identity and physical properties of

the each drug employed, the dosage of drug employed, the desired effect of said drug, the intended application of osmotic device, and the physiological condition to be treated as taught by Faour et al.

Response to Arguments

Applicant argues that Savastano discloses an osmotic device containing an active core, a delay jacket, a semipermeable membrane, and a drug overcoat. It is argued that Savastano does not teach a semipermeable membrane around both active a lag phase release and instant invention teaches a zero order release.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points to claim 20 wherein Savastano teaches an active core, a delay jacket, an additional drug layer that can between the delay jacket and semipermeable membrane. As discussed above, the claims may be interpreted in two ways: one wall encloses both the core and layer or one wall encloses the core and another wall encloses the core. In contrast to Faour et al, Savastano et al was applied using the first interpretation wherein a semipermeable wall encloses the core portion and the layer portion. The examiner suggests modifying the claim language to clarify which interpretation is in fact the invention. As it stands, the claims may be read in either manner. Lastly, the examiner points out that the claim language does not exclude additional coatings such as Savastano' delay jacket.

Rejection of claims 1-3 and 7 under 35 U.S.C. 103(a) as being unpatentable over Savastano et al (5,681,584) in view of Fassihi et al (5,783,212) has been withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

June 2, 2003